

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Riluzole as adjuvant therapy in the treatment of moderate to severe major depression: A double - blind placebo-controlled trial

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of Riluzole as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. 40 adult inpatient who meet the DSM- IV- TR criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 19 will be allocated into two groups. 20 patients will receive Citalopram 40 mg/day plus Riluzole 100mg/day (50 mg bid) and 20 participants will receive Citalopram 40 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started. Depression severity will be assessed by Hamilton Depression Rating Scale which will be the primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307181556N54**

Registration date: **2013-07-18, 1392/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-18, 1392/04/27

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Riluzole as adjuvant therapy in the treatment of moderate to severe major depression: A double - blind placebo-controlled trial

Public title

Riluzole in the treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Presence of Major Depressive Disorder based on DSM-IV criteria; Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 19. Exclusion criteria: 1. Presence of Psychosis; 2. any other diagnosis in Axis I and II; 3. Receiving psychotropic medications; 4. receiving any antidepressants during past one month or ECT during past two months; 5. Presence of hypothyroidism; 6. cardiovascular problems; 7. pregnancy or nursing women; 8. rising liver transaminases to three times the upper limit of normal or higher

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshvarz Blvd

City

Tehran

Postal code**Approval date**

2013-07-13, 1392/04/22

Ethics committee reference number

22192

Health conditions studied**1****Description of health condition studied**

Major Depressive episode

ICD-10 code

F32

ICD-10 code description

Major Depressive episode

Primary outcomes**1****Description**

Severity of depression

Timepoint

Baseline and weeks 2,4 and 6

Method of measurement

Hamilton Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups**1****Description**

Tablet Citalopram 40 mg/day plus Tablet Riluzole 50 mg twice per day as intervention group for 6 weeks

Category

Treatment - Drugs

2**Description**

Tablet Citalopram 40 mg/day plus Tablet placebo as control group for 6 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet, Roozbeh Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

Keshvarz Blvd

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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